Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications

Jerry G. Blaivas,* Rajveer S. Purohit,† James M. Weinberger,‡,§ Johnson F. Tsui,‖ Jyoti Chouhan,‖ Ruhee Sidhu¶ and Kamron Saleem‖

From the Weill Medical College of Cornell University and Urocenter of New York, New York, New York

Purpose: We report our experience with the diagnosis and treatment of refractory synthetic sling complications in women.

Materials and Methods: This is a retrospective study of consecutive women with failed treatments for mesh sling complications. Before and after surgery the patients completed validated questionnaires and voiding diaries, and underwent uroflow with post-void residuals, pad test, cystourethroscopy and video-urodynamic studies. Treatment was individualized, and results were subdivided into the 2 groups of conditions and symptoms. Outcomes were assessed with the Patient Global Impression of Improvement with success classified as a score of 1, improvement as 2 to 3 and failure as 4 to 7.

Results: A total of 47 women 35 to 83 years old (mean 60) had undergone at least 1 prior operation (range 1 to 4) to correct sling complications. Original sling composition was type 1 mesh in 36 patients and types 2 and 3 in 11. Surgical procedures included sling incision, sling excision, urethrolysis, urethral reconstruction, ureteroneocystotomy, cystectomy and urinary diversion, and enterocystoplasty. Median followup was 2 years (range 0.25 to 12, mean 3). Overall a successful outcome was achieved in 34 of 47 patients (72%) after the first salvage surgery. Reasons for failure were multiple for each patient. Of the 13 patients with treatment failure 9 subsequently underwent 14 operations. Success/improvement was achieved in 5 women (56%) after continent urinary diversion (1), continent urinary diversion and cystectomy (1), partial cystectomy and augmentation cystoplasty (1), biological sling and sinus tract excision (1), and vaginal mesh excision (1).

Conclusions: Success after the initial failure of mesh sling complications repair is possible but multiple surgeries may be required. Each symptom should be addressed separately.

Key Words: surgical mesh, suburethral slings, postoperative complications, salvage therapy, urinary incontinence

Abbreviations and Acronyms

LUTSS = Lower Urinary Tract Symptom Score
OAB = overactive bladder
PGI-I = Patient Global Impression of Improvement
Qmax = maximum flow rate
SUI = stress urinary incontinence
TOT = transobturator tape
TVT® = tension-free vaginal tape
UTI = urinary tract infection

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† Financial interest and/or other relationship with Wedgewood Pharmacy.

‡ Correspondence: Institute for Bladder and Prostate Research, New York, New York 10075 (e-mail: james.m.weinberger@gmail.com).

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THE use of mesh for the correction of sphincteric incontinence has increased dramatically during the last 2 decades.[1,2] Its appeal rests in high reported success rates[3] and its comparatively simpler surgical technique which allows for greater numbers of surgeons to perform the surgery.[4] However, the initial enthusiasm for mesh has been tempered by increasing concerns about potential complications. In 2008 the Food and Drug Administration issued a public health warning about complications of synthetic mesh slings between 2005 and 2007.[5] By 2010 nearly 4,000

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reports of complications were submitted to the Food and Drug Administration (average 958 cases per year). The most frequent complications during this time were vaginal mesh erosion, pelvic pain, UTI, dyspareunia, organ perforation, voiding dysfunction and recurrence of incontinence.

The management of mesh sling complications is fraught with complexity and even in the most experienced hands the outcomes are suboptimal. We present our data on the presentation, surgical management and outcomes of salvage mesh repairs using validated outcome instruments at a tertiary care facility.

MATERIALS AND METHODS

This is a retrospective observational study of consecutive patients who presented with complications from synthetic mesh sling surgery and underwent at least 1 prior attempt at repair of the complication. Medical records from 1997 to 2012 were reviewed and patients were excluded from analysis if they did not undergo surgery and/or if they did not have at least 1 prior attempt at repair.

Baseline assessment at presentation included a 24-hour bladder diary, pad test (for incontinent patients), urinary flow rate, post-void residual volume, cystourethroscopy, videourodynamic studies and the validated LUTSS questionnaire. Treatment was individualized to particular complications. Postoperatively all patients completed a bladder diary, pad test (for incontinent patients), LUTSS questionnaire, uroflow and measurement of post-void residual volume, and the PGI-I for each preoperative symptom. Results were analyzed by presenting symptom and by anatomical condition (table 1). The primary outcome measure for symptoms was the PGI-I. A score of 1 correlated with success, a score of 2 to 3 indicated improvement and a score of 4 to 7 indicated failure. For anatomical conditions (urethral stricture, fistula, mesh erosion) the authors ascribed success, improvement or failure based on the specifics of each case.

Table 1. *Presenting symptoms and complications*

	No. (%)
Presenting symptoms:	
OAB	33 (70)
SUI	25 (55)
Recurrent UTI	10 (21)
Pelvic pain/dysuria	16 (34)
Obstructive symptoms	4 (9)
Vaginal discharge	8 (17)
Presenting conditions:	
Urethral obstruction	24 (51)
SUI	23 (49)
Bladder/urethral erosion	11 (23)
Fistula	8 (17)
Bladder/urethral stone	5 (11)
Vaginal extrusion	4 (9)
Ureteral injury	2 (4)

RESULTS

Overall 54 women were identified, of whom 5 were excluded from analysis because they had not undergone prior surgery for the mesh complication and 2 were excluded because they elected no further surgery. One patient was initially operated on at our institution and the remaining patients were referred from elsewhere. None of the original surgeries was performed by any of the authors. Mean patient age at presentation was 60 years (range 35 to 83). The time from mesh placement to the diagnosis of a complication was 1.99 years (range 1 month to 8 years). The mean number of attempts at repair before presentation was 1.3 (range 1 to 4). Type 1 (monofilament, macroporous) mesh was used in 36 patients (76.5%), and types 2 and 3 (multifilament, microporous) were used in 11 (23.5%). A retropubic approach was used in 41 (87%) women and a transobturator approach was used in 6 (13%). Table 1 lists the mesh complications by symptom and anatomical complication, and table 2 lists the types of salvage procedures performed.

Representative cases of sphincteric incontinence, urethral obstruction, urethral and bladder erosion, and vaginal extrusion are seen in figures 1 through 5, respectively. Followup ranged from 3 months to 12 years (mean 3 years, median 2 years). Time from salvage surgery to failure ranged from 4 months to 8 years with a mean of 2.2 years and a median of 2 years. Overall success/improvement was achieved in 34 of 47 (72%) patients after a single salvage operation. Reasons for failure were multiple for each patient, including refractory pain (9), mesh extrusion (8), OAB (8), mixed incontinence (2), urethral obstruction (1) and recurrent fistula (1). Of the 13 patients with initial treatment failure 9 subsequently underwent a total of 14 subsequent procedures, and success/improvement was achieved in 5 (56%) after continent urinary diversion (1); continent urinary diversion and cystectomy (1); partial cystectomy, ureteroneocystotomy and augmentation cystoplasty (1); biological sling and sinus tract excision (1); and vaginal mesh excision (1). Two patients underwent continent urinary diversion because of refractory low bladder compliance, detrusor overactivity and recurrent UTI after TVT. One patient underwent partial cystectomy,

Table 2. *Types of procedures performed*

	No.
Sling excision ± urethrolysis	16
Sling excision ± urethral reconstruction (including fistula repair) ± autologous fascial sling + Martius flap	14
Sling incision	10
Cystotomy ± partial cystectomy	5
Ureteroneocystotomy	2

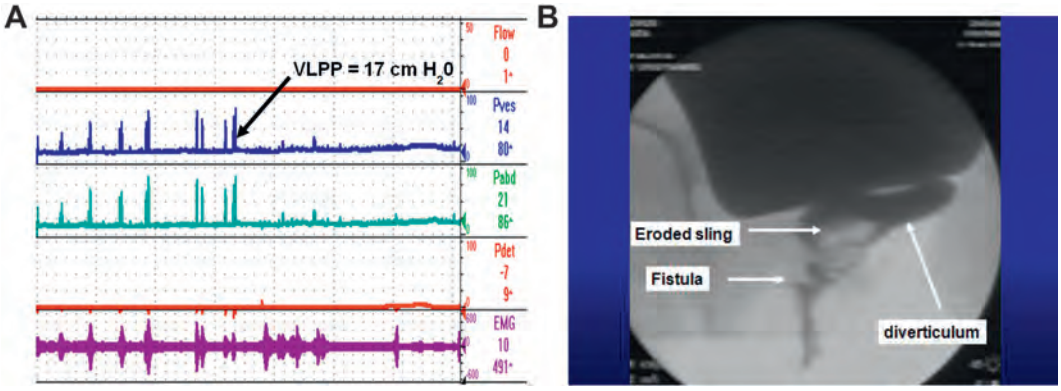

Figure 1. Videourodynamic study in 65-year-old woman who underwent urethral diverticulectomy and retropubic synthetic sling (type unknown). At cystoscopy large urethrovaginal fistula was visualized at bladder neck. *A*, urodynamic tracing showed vesical leak point pressure of 17 cm H_2O. *VLPP*, Valsalva leak point pressure. *Pves*, vesical pressure. *Pabd*, abdominal pressure. *Pdet*, detrusor pressure. *EMG*, electromyogram. *B*, stress cystogram showed sphincteric incontinence, large urethral diverticulum and urethrovaginal fistula. Patient underwent sling excision, urethrovaginal fistula repair with Martius flap interposition and autologous fascial pubovaginal sling. At postoperative year 6 PGI-I was 1 and patient denied having any lower urinary tract symptoms.

ureteroneocystotomy and augmentation cystoplasty because of mesh erosion of the sling into the bladder with resulting granuloma involving the bladder wall and ureteral obstruction. Per the patient specific PGI-I scores, success was ultimately achieved in 39 of 47 patients (82%) (table 3).

DISCUSSION

Synthetic mesh slings have become the most common operation for the treatment of sphincteric incontinence in women.[1] More than 1 million TVT procedures were performed between 1996 and 2007.[2] Despite a reported success rate of 84% for TOT slings and 88% for TVT slings in the most recent Cochrane review,[6] complications are significant and likely underreported. Studies suggest substantially higher complication rates than what has been reported in the peer reviewed literature.[2,7]

Only 1 patient in this series was operated on at our institution and there is no institutional database, so it was not possible for us to determine the incidence of mesh sling complications, and we acknowledge that our highly select series may overstate the incidence of mesh sling complications by implication. Nevertheless, we do believe that there is a small cohort of patients whose lives have been unalterably changed for the worse as a complication of these seemingly trivial and easy to perform operations. Given the increasing number of mesh sling operations performed and the complexity

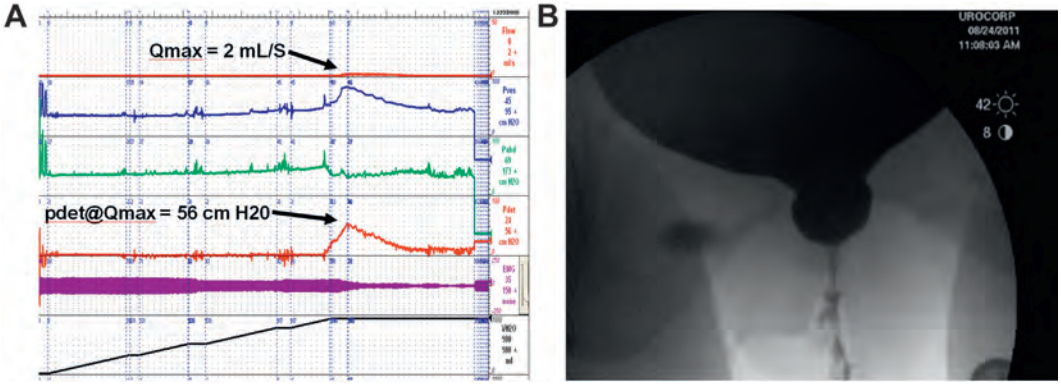

Figure 2. Urethral obstruction 2 years after SPARC™ sling. At surgery sling was embedded in urethral wall but did not erode. *A*, urodynamic tracing showed severe urethral obstruction, Blaivas-Groutz nomogram type 2. *pdet@Qmax*, detrusor pressure at maximum flow rate. *Pves*, vesical pressure. *Pabd*, abdominal pressure. *Pdet*, detrusor pressure. *EMG*, electromyogram. *VH_2O*, volume of water. *B*, x-ray at Qmax showed obstruction in distal third of urethra. Patient underwent excision of suburethral portion of sling and subsequently voided normally (Qmax 19 ml per second, voided volume 150 ml, post-void residual 49 ml). However, patient experienced sphincteric incontinence and underwent successful autologous fascial sling 4 months later.

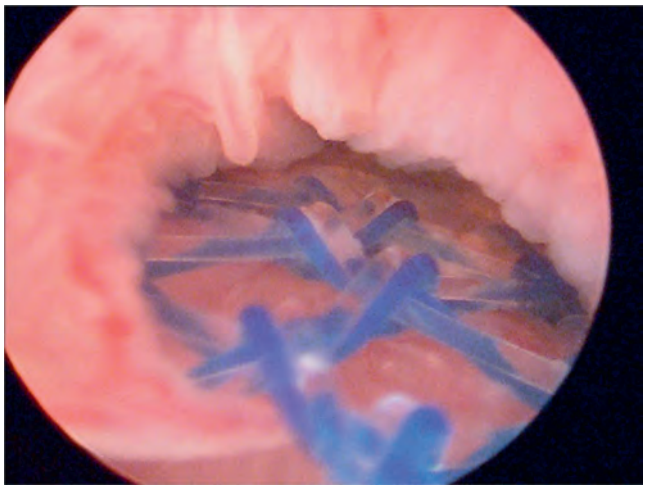

Figure 3. Urethral erosion of TVT in 48-year-old woman 1 year postoperatively. At surgery all tape was removed from affected site without need for reconstruction. At postoperative year 1 she reported PGI-I of 1.

of surgery to repair the complication(s), we believe that there will be an increasing number of patients in whom initial treatments failed and an increasing number of "mesh cripples." Our study is highly selective and is hardly representative of the typical case. However, it does shed some light on the severity and refractory nature of these problems.

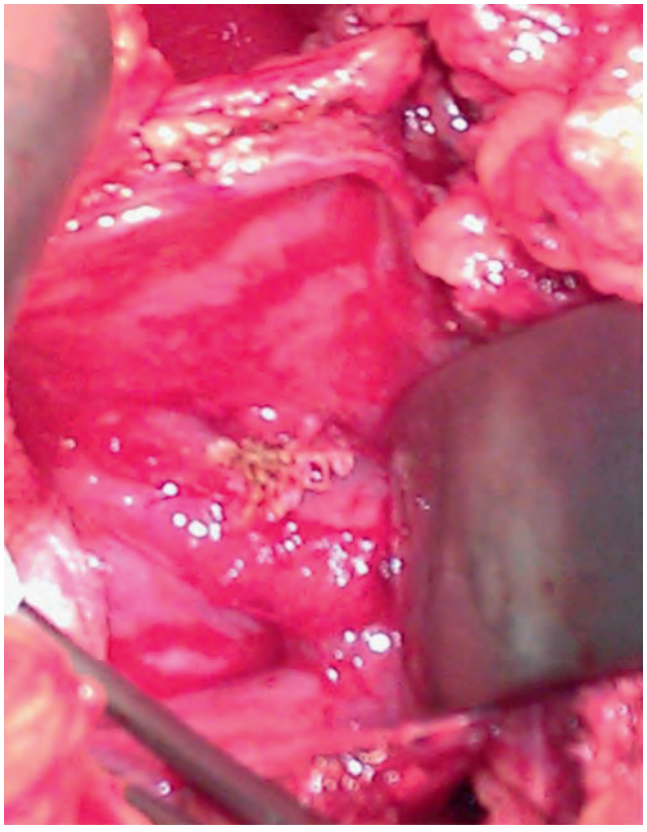

Figure 4. Bladder erosion 7 years after TVT

Figure 5. Vaginal extrusion of TOT sling with granuloma

The etiology of mesh sling complications is a matter of conjecture. Urethral obstruction and/or erosion have 3 potential causes, namely 1) the surgeon simply pulls the sling too tight at surgery, 2) a correctly placed sling contracts with time due to tissue ingrowth[8] and 3) faulty surgical technique results in placement of the sling directly into the urinary tract. Depending on the thickness of the vaginal wall, it may be difficult to place the mesh accurately. If it is placed too superficially (ie between the vaginal epithelium and the pubocervical fascia), vaginal extrusion might occur. Conversely, sling placement that is too deep (ie to the pubocervical fascia) might cause urethral or bladder erosion.

Regardless of the original cause, salvage treatment of urethral obstruction, erosion and/or fistula depends on intraoperative findings. In most patients it is possible to separate the remnant of

Table 3. *Outcomes by symptom complex and condition resolution*

	No. Success (%)	No. Improvement (%)	No. Failure (%)
Symptom (No.):			
OAB (35)	6 (17)	20 (57)	9 (26)
SUI (28)	11 (39)	12 (43)	5 (18)
Pelvic pain (18)	5 (28)	4 (22)	9 (50)
Discharge/hematuria (7)	4 (57)	2 (29)	1 (14)
Voiding dysfunction (4)	3 (75)	1 (25)	0 (0)
Condition (No.):			
Urethral obstruction (24)	16 (66)	6 (25)	2 (9)
Fistula (14)	13 (93)	0 (0)	1 (7)
SUI (25)	10 (40)	10 (40)	5 (20)
Vaginal extrusion (12)	4 (33)	0 (0)	8 (67)
Bladder/urethral erosion (11)	10 (91)	0 (0)	1 (9)
Ureteral injury (2)	2 (100)	0 (0)	0 (0)

the sling that was not previously excised from the urethra with sharp dissection and simply incise or excise the suburethral portion. If the sling is adherent to the wall or has eroded through the wall, we believe it best to excise as much of the sling as possible through the vagina and repair or reconstruct the urethra as necessary. If there is extensive periurethral scarring, urethrolysis may be necessary.

Determining the need for another sling and/or Martius flap must be individualized based on local anatomy and patient/surgeon preference. We strongly believe that when another sling is needed, it should be biological (we prefer autologous rectus fascia),[9] and have found that positioning the Martius flap between the reconstructed urethra and sling provides a good buffer against recurrence without compromising continence outcomes.[10] The American Urological Association Guideline on the treatment of SUI specifically warns against using another synthetic mesh sling once urethral erosion has occurred.[11] In the present study the success rates for treating urethral obstruction and fistula were high at 93% and 91%, respectively. Other studies have shown a 70% success rate for mesh slings[12] as well as an 87% success rate[13] and an 84% success rate for urethrolysis for obstruction after biological and mesh slings, respectively.[14]

For bladder erosions of the mesh (with or without stones) several approaches have been described. However, there are no meaningful data and no realistic method of comparing the results. Most commonly, surgeons have described transurethral removal with a scissors and/or grasping forceps, laser lithotripsy and vaporization of the mesh, a combined percutaneous and transurethral approach as well as combined transvaginal and suprapubic approaches.[15–17]

Our experience with the transurethral and percutaneous approach is limited. We have noted that in many instances of bladder and urethral perforation, the mesh crosses the wall of the viscus obliquely so that if one removes just the portion that is visible in the bladder, recurrence may be inevitable in some patients. After a recurrence we advocate removing all of the mesh from the offending site (vaginal and suprapubic). It is generally straightforward to remove the retropubic and vaginal portions of the sling, but for retropubic slings the portion adjacent to the bladder neck is particularly challenging, and may require a combined retropubic and vaginal approach.

The cause of pelvic pain and dyspareunia has also not been well studied. If the vagina is scarred, narrowed and tender, with or without mesh extrusion, the cause of the dyspareunia may be obvious. However, when that is not the case, proposed causes of refractory pain are nerve entrapment, infection and foreign body granuloma.[18,19]

Pelvic pain and dyspareunia pose particularly difficult challenges, and despite our best efforts treatment was unsuccessful in half of the patients. We hypothesize that inadequate removal of the mesh may be a cause of persistent pain, and we have been particularly frustrated by our inability to address this in patients with TOT slings and in those who have undergone mesh prolapse repairs. Reynolds et al reported a 63% improvement in pain symptoms after an attempt at complete removal of the mesh from sling and prolapse surgeries.[20] The discrepancy could be attributed to the different techniques used for removal (traditional vs obturator foramen dissection) or to the small patient population in the study by Reynolds et al.

There are several weaknesses in our study. The primary outcome measure, the PGI-I, was administered with reference to patient symptoms before the salvage procedure and not compared to patient status before the original sling surgery. We believe that most patients who reported improvement after the salvage surgery were actually worse off than before the initial mesh sling surgery. In addition, the retrospective nature of the study could be considered a weakness. Also, none of the patients underwent the original sling operation at our practice so we are unable to assess the incidence, natural history and time course of these complications. The followup was too short and it is likely that some of our successes will ultimately be failures in the future.

Strengths of this review include the fairly large size of our series, the use of well-defined and validated outcome tools that assessed subjective and objective criteria, and reasonably good followup.

No outcome instruments have been specifically devised to assess treatment of mesh complications. Most studies have defined success postoperatively based on patient subjective complaints.[21–23] In this study we assessed each symptom and condition separately. For incontinence, the Simplified Urinary Incontinence Outcome Score was used as the primary outcome measure[24] and for OAB the overactive bladder symptom score was used.[25] Voiding dysfunction and obstructive symptoms were assessed with a flow and post-void residual as well as the LUTSS questionnaire. A patient reported outcome, the PGI-I, was used to evaluate pelvic pain and dyspareunia as well as to provide an overall subjective appraisal of the success/failure of treatment.[26]

Using these outcome instruments, overall success/improvement was achieved in 34 of 47 (72%) patients after a single salvage operation and in 82%

after multiple operations. For individual symptoms and conditions, the success/improvement rate ranged from 50% (for pain) to 100% (for urethral obstruction). Padmanabhan et al detailed vaginal excision with subjective cure in 75% and improvement in 21%.[23] For repair of lower urinary tract erosions 53% reported subjective cure and 35% indicated improvement. Other studies used incontinence quality of life questionnaires, eg the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7), in conjunction with a stress test.[27]

CONCLUSIONS

The true incidence of refractory mesh sling complications is not known, but it is evident that they do occur, and may be severe and lifestyle altering. Most patients have multiple symptoms and conditions. Nevertheless, some degree of success is possible in most patients, and for some conditions such as urethral obstruction, fistula, bladder and urethral erosions a high success rate is possible. The most difficult problem to treat is pain, with only 28% of patients with pain considering the salvage operation a success.

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